



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0115]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0601. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7726, Ila.Mizrachi@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Manufactured Food Regulatory Program Standards--(OMB Control Number 0910-0601)--

Extension

In the Federal Register of July 20, 2006 (71 FR 41221), FDA announced the availability of a draft document entitled "Manufactured Food Regulatory Program Standards (MFRPS)." These draft program standards are the framework that States should use to design and manage its manufactured food program. The implementation of the standards will be negotiated as an option for payment under the State food contract. States that are awarded this option will receive up to \$25,000 over a period of 5 years to fully implement the program standards. Additionally, 26 States may receive up to \$300,000 each year for a period of 5 years to be in compliance with the 10 standards.

In the first year of implementing the program standards, the State program conducts a baseline self-assessment to determine if they meet the elements of each standard. The State program should use the worksheets and forms contained herein; however, it can use alternate forms that are equivalent. The State program maintains the documents and verifying records required for each standard. The information contained in the documents must be current and fit-for-use. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) The individual element of documentation requirement of the standard that was not met; (2) improvements needed to meet the program element or documentation requirement of the standard; and (3) projected completion dates for each task.

In the Federal Register of February 19, 2013 (78 FR 11651), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Departments of Agriculture or Health	44	1	44	303	13,332

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden has been calculated to 303 hours per respondent. This burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 10 standards contained in MFRPS. The hours per respondent will remain the same as implementation to account for continuing improvement and self-sufficiency in the program.

Dated: July 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.